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10/766,503	01/28/2004	Dan E. Fischer	7678.811	3475
22913	7590	05/25/2007	EXAMINER	
WORKMAN NYDEGGER (F/K/A WORKMAN NYDEGGER & SEELEY) 60 EAST SOUTH TEMPLE 1000 EAGLE GATE TOWER SALT LAKE CITY, UT 84111			SINGH, SATYENDRA K	
		ART UNIT	PAPER NUMBER	
		1657		
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		05/25/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/766,503	FISCHER, DAN E.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Satyendra K. Singh	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 October 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 and 16-27 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10, 14 and 15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 28 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 4/22/04; 5/1/06.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

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## DETAILED ACTION

Applicant's response and amendments to the claims filed with the office on October 13<sup>th</sup> 2006 is duly acknowledged.

### ***Election/Restrictions***

Applicant's election **without traverse** of group I (claims 1-10, 14 and 15; drawn to a delivery system for promoting bone growth) in the reply filed on October 13<sup>th</sup> 2006 is acknowledged. However, applicants have introduced an amendment to the pending claims in which claims 11 (group II) and claim 16 (group III) have been made to depend from claim 1 (group I), and claims 25-27 (group IV) have been cancelled (see remarks, page 5, 1<sup>st</sup> paragraph, in particular) in an attempt to link them with the invention of group I (as set forth originally in the restriction/election requirement sent by the office on 09/14/2006, page 2, in particular), which is not found to be appropriate, as they are drawn to distinct compositions (group I and group III) and methods (group II and group IV), and would put an undue burden on the examiner for search and examination of all the distinct groups claimed in the application (as previously discussed in the office action sent by the Examiner on 09/14/2006).

Therefore, Claims 11-13 and 16-27 (groups II-IV) are withdrawn from further consideration.

Claims 1-10, 14 and 15 (the elected invention of group I) are examined on their merits in this office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10, 14 and 15 are rendered indefinite by the use of the term "**system**" because it is unclear exactly what applicant is attempting to claim. A system could arguably be a process, a machine or a product. It does not appear that applicant is attempting to claim a method, but if so, applicant has failed to properly define the invention by positively reciting the steps of the inventive process. It would appear that applicant's system is a product or an apparatus but the claims fail to adequately define such an invention. The instant claims (see instant claim 1, in particular) fail to set forth a defined structure for the system comprising a "covering" formed of a water gelatinizable material, and its structural relationship with the "bone growth promoting material contained within", and as such does not adequately define a product or an apparatus. Appropriate explanation/correction is required.

For examination purposes, herein, the instant claims are interpreted by the Examiner as being drawn to a composition comprising "water absorbing gelatinizable material" (suitable to work as a covering material) and a "bone growth promoting material" contained within said gelatinizable material.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10, 14 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A “**system**” is not statutory subject matter. Applicant should properly claim the instant invention as indicated in the statute. Applicant would appear to be claiming either a product or an apparatus but there exists no structural elements/relationships between the components of the invention that would be necessary for the invention to be considered as an apparatus, or a product. Appropriate explanation/correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**1. Claims 1,3, 5-7, 9-10 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy (US 5,292,253; [A]).**

The instant claims are interpreted by the Examiner (see discussion above) as being drawn to a **composition** (and **method of using** said composition) comprising “water absorbing gelatinizable material” (suitable to work as a covering material) and a “bone growth promoting material” contained within said gelatinizable material, wherein the water absorbing gelatinizable material is resorbable (claim 3), wherein bone growth promoting material is as specifically recited in instant claim 5, wherein the delivery system has an elongated sausage-like or pillow like configuration (claims 6 and 7), wherein the delivery system comprises at least one of fibrin powder and chopped adhesive gauze (claims 9-10), and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (claims 14-15).

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Levy [A] discloses a composition (and method of using said composition; see Levy, abstract, summary of the invention, and claims, in particular) comprising "water absorbing gelatinizable material" (suitable to work as a covering material such as collagen, gelatin, fibrin, or plasmin; see column 1, lines 64-68, in particular) and a "bone growth promoting material" (such as calcium phosphate, or derivatives thereof, or hydroxyapatite; see Levy, column 2, lines 7-9, in particular) contained within said gelatinizable material (see Levy, column 3-4, in particular), wherein the water absorbing gelatinizable material is resorbable, wherein bone growth promoting material is as specifically recited in instant claim 5, wherein the delivery system has an elongated or pillow like configuration (in the absence of any defined structural features/parameters in the claims for such "sausage-like" or "pillow-like configuration"; see figures 1-2, in particular), wherein the delivery system comprises at least one of fibrin powder (see Levy, claim 5, in particular) and chopped adhesive gauze; and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. repair of periodontal pockets in the gingival; see Levy column 1, lines 64-68, columns 3-4, and claims, in particular).

**2. Claims 1,3-7, 9-10 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (US 5,707,962; [B]).**

The instant claims are interpreted by the Examiner (see discussion above) as being drawn to a composition (and method of using said composition) comprising "water absorbing gelatinizable material" (suitable to work as a covering material) and a "bone growth promoting material" contained within said gelatinizable material, wherein the water absorbing gelatinizable material is resorbable or non-resorbable (claims 3-4), wherein bone growth promoting material is as specifically recited in instant claim 5, wherein the delivery system has an elongated sausage-like or pillow like configuration (claims 6 and 7), wherein the delivery system comprises at least one of fibrin powder and chopped adhesive gauze (claims

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9-10), and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (claims 14-15).

Chen et al [B] disclose a **composition** (and method of using said composition; see Chen et al, abstract, summary of the invention, and claims, in particular) comprising "water absorbing gelatinizable material" (suitable to work as a covering material such as collagen, gelatin, or other polyamino acids; see column 3, 1<sup>st</sup> paragraph, in particular) and a "bone growth promoting material" (such as calcium phosphate, or derivatives thereof, or hydroxyapatite; see Chen et al, column 3, 1<sup>st</sup> paragraph and column 4, 2<sup>nd</sup> paragraph, in particular) contained within said gelatinizable material (in the form of a sponge or fleece, or other desired shapes containing demineralized bone particles/powder; see Chen et al, column 4, in particular), wherein the water absorbing gelatinizable material is resorbable or non-resorbable (see Chen et al, column 3, 1<sup>st</sup> paragraph, in particular), wherein bone growth promoting material is as specifically recited in instant claim 5, wherein the delivery system has an elongated or pillow like configuration (in the absence of any defined structural features/parameters in the claims for such "sausage-like" or "pillow-like configuration"; see Chen et al, column 4, last paragraph, in particular), wherein the delivery system further comprises at least one of fibrin (see Chen et al, column 5, 4<sup>th</sup> paragraph, in particular); and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. repair of periodontal pockets in the gingival; see Chen et al, abstract, and claim13, in particular).

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**3. Claims 1,4, 6-7 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashman et al (US 4,728,570; [C]).**

The instant claims are interpreted by the Examiner (see discussion above) as being drawn to a **composition** (and **method of using** said composition) comprising "water absorbing gelatinizable material" (suitable to work as a covering material) and a "bone growth promoting material" contained within said gelatinizable material, wherein the water absorbing gelatinizable material is non-resorbable (claim 4), wherein the delivery system has an elongated sausage-like or pillow-like configuration (claims 6 and 7), and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (claims 14-15).

Ashman et al [C] disclose a **composition** (and method of using said composition; see Ashman et al, abstract, summary of the invention, and claims, in particular) comprising "water absorbing gelatinizable material" (suitable to work as a covering material such as methacrylate derivatives, PMMA and MHEMA; see Ashman et al, column 2, summary of the invention, in particular) and a "bone growth promoting material" (such as calcium hydroxide; see Ashman et al, abstract, summary, examples, and claims, in particular) contained within said gelatinizable material (prosthetic implants formed in a variety of shapes and forms; see Ashman et al, column 3, lines 50-55, in particular), wherein the water absorbing gelatinizable material is non-resorbable, and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. repair of periodontal pockets in the gingival; see Ashman et al, column 1, lines 18-20, column 3, lines 58-65, and claims 7 and 13, in particular).

**4. Claims 1-7 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Tormala et al (US 4,863,472; [D]).**

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The instant claims are interpreted by the Examiner (see discussion above) as being drawn to a **composition** (and **method of using** said composition) comprising "water absorbing gelatinizable material" (suitable to work as a covering material) and a "bone growth promoting material" contained within said gelatinizable material, wherein the water absorbing gelatinizable material is resorbable or non-resorbable, wherein bone growth promoting material is as specifically recited in instant claim 5, wherein the delivery system has an elongated sausage-like or pillow like configuration; and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth.

Tormala et al [D] disclose a composition (and method of using said composition) comprising "water absorbing gelatinizable material" (suitable to work as a covering material, such as polyglycolide, cellulose derivatives, or cross-linked collagen derivatives such as cat gut; see Tormala et al, columns 3-4, in particular) and a "bone growth promoting material" contained within said gelatinizable material (see Tormala et al, abstract and claims, in particular), wherein the water absorbing gelatinizable material is resorbable or non-resorbable, wherein bone growth promoting material is as specifically recited in instant claim 5 (such as synthetic ceramic powders, or hydroxyapatite; see column 8, example 2, in particular), wherein the delivery system has an elongated sausage-like or pillow like configuration (in the absence of any defined structural features/parameters in the claims for such "sausage-like" or "pillow-like" configuration; see Tormala et al, figures 1-3 and column 5, 3<sup>rd</sup> paragraph, in particular), and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Tormala et al, columns 5-6, in particular).

**5. Claims 1, 3, 5-7 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverberg (US 4,755,184; [E]).**

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The instant claims are interpreted by the Examiner (see discussion above) as being drawn to a **composition** (and **method of using** said composition) comprising "water absorbing gelatinizable material" (suitable to work as a covering material) and a "bone growth promoting material" contained within said gelatinizable material, wherein the water absorbing gelatinizable material is resorbable, wherein bone growth promoting material is as specifically recited in instant claim 5, wherein the delivery system has an elongated sausage-like or pillow like configuration, and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth.

Silverberg [E] a composition (and method of using said composition) comprising "water absorbing gelatinizable material" (suitable to work as a covering material such as a casing made from polyglycolide in the form of a mesh, or collagen or cellulose; see abstract, summary of the invention, column 3, lines 31-55, and claims, in particular) and a "bone growth promoting material" contained within said gelatinizable material (such as hydroxyapatite; see examples, column 4-5, in particular), wherein the water absorbing gelatinizable material is resorbable, wherein bone growth promoting material is as specifically recited in instant claim 5, wherein the delivery system has an elongated sausage-like or pillow like configuration (see figure1, in particular) and is gas sterilized prior to surgical applications (see column 5, 1<sup>st</sup> paragraph, in particular); and a method of promoting bone growth comprising providing said delivery system of claim 1, and placing the delivery system adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Silverberg, column 4 and figure 3-5, in particular).

As per MPEP 2111.01, *during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-10, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverberg (US 4,755,184; [E]) taken with Tormala et al (US 4,863,472; [D]) in view of Levy (US 5,292,253; [A]) and Vyakarnam et al (US 6,306,424 B1; [F]).

Claims are interpreted by the Examiner (see discussion above) as being drawn to a **composition** (and **method of using** said composition) comprising "water absorbing gelatinizable material" (suitable to work as a covering material) and a "bone growth promoting material" contained within said gelatinizable material (see instant claims 1-10, 14 and 15).

The teachings of Silverberg [E] and Tormala et al [D] have been discussed above in details, and are further relied upon in the same manner, herein.

However, a delivery system further comprising an adhesive such as **fibrin** powder (see instant claims 9-10); or a delivery system, which is stored within **moisture-**

**resistant packaging** is not explicitly disclosed by the referenced inventions of Silverberg and Tormala et al.

The teachings of Levy [A] are discussed above in detail, and are further relied upon in the same manner, herein. Levy explicitly discloses the use of **fibrin** with or without collagen (see column 3, lines 24-29, and claims, in particular) to form a protein gel that can be combined with calcium-containing materials such as hydroxyapatite and/or calcium phosphate to prepare the implant for filling the void or defects for the repair of tooth and bone tissues.

Vyakarnam et al [F] disclose the routine practice of packaging implant materials after sterilization in an appropriate sterilized, **moisture-resistant package** for shipment and use in hospitals and other health care facilities (see column 19, 3<sup>rd</sup> paragraph, in particular).

Therefore, given the detailed disclosures of the components and the structure of the delivery system (as claimed in the instant application) in the above cited prior art references, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the delivery system/composition taught by Silverberg (taken with the disclosure of Tormala et al) such that it further comprises an adhesive such as fibrin, and is stored within a moisture-resistant packaging as explicitly suggested and demonstrated by the disclosures of Levy and Vyakarnam et al with a reasonable expectation of success in order to provide a gelling component or a glue in the composition as well as to avoid contamination of the delivery system during storage (both the limitations are deemed to be routinely practiced in the implantation art).

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As per MPEP 2144.06, "It is *prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.*" *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069; 1072 (CCPA 1980).

As per MPEP 2144.06, *In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents.* *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

### **Conclusion**

**NO claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Satyendra K. Singh  
Patent Examiner  
Art unit 1657

  
SANDRA E. SAUCIER  
PRIMARY EXAMINER